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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,143

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Ronald James Jandacek

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT

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1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,143	Applicant(s) JANDACEK ET AL.	
	Examiner Maureen M. Wallenhorst	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/17/06</u> . | 6) <input type="checkbox"/> Other: ____. |

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1. The abstract of the disclosure is objected to because the abstract from the corresponding PCT application should be placed onto a separate sheet. Correction is required. See MPEP § 608.01(b).

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 3-6 and 8-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of measuring total dietary fat absorption using a composition comprising a dietary fat and a sucrose polyester non-absorbable fat, in particular sucrose behenate, does not reasonably provide enablement for a method of measuring total dietary fat absorption using a composition comprising a dietary fat and any non-absorbable fat other than a sucrose polyester. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification, as originally filed, only describes the method for measuring total dietary fat absorption in terms of using a sucrose polyester, in particular sucrose behenate, as a marker comprising a non-absorbable fat. No other marker materials comprising a non-absorbable fat are mentioned in the specification, and therefore, one of ordinary skill in the art could not be certain that any non-absorbable fat material other than a sucrose polyester, and in particular sucrose behenate, would work in the invention to measure total dietary fat absorption by the digestive tract of a subject.

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4. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite since the claim recites a non-absorbable fat as the marker. However, the specification indicates that the non-absorbable fat marker is a sucrose polyester such as sucrose behenate, and this material is well-known in the art to be a synthetic, fat-like material or fat substitute material. It is not an actual naturally occurring fat material, and therefore, the description given for the marker in claim 1 is indefinite. See this same problem in claim 5.

Regarding claim 2, the phrases "preferably" and "more preferably" render the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). See this same problem in claims 4, 5, 7, 8 and 9.

On line 3 of claim 4, the phrase "the fecal matter" lacks antecedent basis. On line 4 of claim 4, the phrase "the sample collected from the subject" lacks antecedent basis.

In part d) of claim 5, the phrase "the non-absorbable fat marker" should be changed to either --the non-absorbable fat-- or --the marker-- so as coincide with the language used in part a) of the claim.

5. Claim 10 provides for the use of sucrose polyester comprising behenate fatty acid chains, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 10 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 5-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Mattson et al (US 3,600,186).

Mattson et al teach of a low calorie fat-containing food composition comprising triglyceride dietary fat and a non-absorbable fat material in the form of a fatty acid ester compound having at least 4 fatty acid ester groups. From about 10% to about 100% of the total fat in the composition comprises a sugar or sugar alcohol fatty acid ester having at least 4 fatty

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acid ester groups, each of the fatty acids having from about 8 to about 22 carbon atoms. The sugar or sugar alcohol fatty acid esters are less digested or absorbed than normal triglyceride fat in the intestinal tract. Examples of the sugar in the sugar fatty acid ester include glucose and sucrose. The four hydroxyl groups of the sugar compound are esterified with a fatty acid having from about 8 to about 22 carbon atoms. When 22 carbon atoms are present in the sugar compound, the compound is sucrose behenate. The test composition can also comprise protein (i.e. casein) and carbohydrates (i.e. flour). The test composition can contain 10%, 25% or 100% of the non-absorbable fat compound with the remainder of the fat portion of the composition being dietary triolein. See lines 9-72 in column 2 and columns 5-6 in Mattson et al. Mattson et al also teach that the test composition including the dietary fat and the non-absorbable sugar fatty acid ester material can be used in a fat balance experiment that measures the total dietary fat absorption by the digestive tract of a subject. In the experiment, a subject such as a rat is fed a test meal comprising the test composition (i.e. a combination of dietary fat and the non-absorbable sugar fatty acid ester material such as sucrose polyester), and a sample of fecal matter is collected from the subject at a time point after the test meal has been ingested. The amount of fat eaten and the amount of fat in the feces are determined. The difference between these two values is the amount of fat absorbed by the digestive tract of the subject. Mattson et al teach that the portion absorbed of the amount fed expressed as a percentage is the coefficient of absorbability and is an indication of the relative available calories of the test composition. See lines 32-43 in column 4 of Mattson et al.

9. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Young et al (US 5,085,884).

Young et al teach of a reduced calorie food composition comprising a digestable triglyceride fat or oil and a nondigestable fat component. The nondigestable component comprises nondigestable solid or liquid polyol fatty acid polyesters having ester groups comprising combinations of unsaturated (C12 or higher) and/or short chain (C2-C12) saturated fatty acid radicals and long chain (C20 or higher) saturated fatty acid radicals. The nondigestable fat component is a liquid or solid sugar fatty acid polyester, wherein the sugar can be sucrose. The sugar fatty acid polyester contains at least 4 fatty acid ester groups which are nondigestable and consequently non-absorbable by the human body. The sugar starting material of these polyesters are esterified with fatty acids containing from 2 to 24 carbon atoms, preferably 8 to 22 carbon atoms. Examples of the fatty acids include behenic acid, thus making the non-absorbable compound a sugar (i.e. sucrose) behenate. Young et al teach of the manufacture of sucrose C12-C22 polyesters such as sucrose behenate in the examples. See the abstract, lines 20-50 in column 4, lines 15-59 in column 7, lines 1-11 in column 8 and columns 13-14 in Young et al.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mattson et al in view of Young et al. For a teaching of Mattson et al and Young et al, see previous paragraphs in this Office action.

Mattson et al fail to teach that the non-absorbable fat material in the test composition used in the method of determining the fat absorption by the digestive tract of a subject can be sucrose behenate. However, based upon the combination of Mattson et al and Young et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use sucrose behenate as the non-absorbable fat material in the test composition taught by Mattson et al since Mattson et al teach that the non-absorbable fat material is a sugar fatty acid ester compound having at least 4 fatty acid ester groups where the sugar can be sucrose and the fatty acids have from about 8 to about 22 carbon atoms, and Young et al teach that a known nonabsorbable fat compound for use in ingestible test compositions includes sucrose behenate that is encompassed by the teaching of Mattson et al since sucrose behenate is a sugar fatty acid ester compound having sucrose and at least 4 fatty acid ester groups with 22 carbon atoms each.

13. Claims 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mattson et al in view of Janghorbani et al (US 6,006,754, submitted in the Information Disclosure Statement filed on July 17, 2006). For a teaching of Mattson et al, see previous paragraphs in this Office action. Mattson et al fail to teach that test composition fed to the subject in the method for determining the dietary fat absorption by the digestive tract of the subject contains a colorant material.

Janghorbani et al teach of a method and composition for measuring fat absorption. The method comprises the steps of feeding a person a composition comprising a labeled dietary fat, a non-absorbable marker and a means for coloring stool, allowing the composition to travel through the digestive tract of the person, monitoring the stool from the person for the appearance of the coloring means, collecting stool containing the coloring means, and measuring the amount of the non-absorbable marker and labeled dietary fat in the colored stool to determine the portion of fat digested and/or absorbed by the person. The dietary fat includes a triglyceride, the non-absorbable marker includes a non-absorbable salt containing an element from the lanthanide group, and the coloring means includes a dye such as carmine red. See lines 1-26 and 53-67 in column 3, lines 1-32 in column 4 and lines 24-27 in column 7 of Janghorbani et al. Stool samples from the person are collected for five days after administration of the composition.

Based upon the combination of Mattson et al and Janghorbani et al, it would have been obvious to one of ordinary skill in the art to include a colorant material such as a dye in the test composition taught by Mattson et al used for determining the dietary fat absorption by the digestive tract of a subject in order to provide an easy means to identify the portion of the subject's stool to collect and analyze for fat content after the test composition has been ingested, in accordance with the teaching of Janghorbani et al.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Bernhardt et al and Naber et al who teach of low calorie fat compositions comprising sucrose polyester.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1797

mmw

June 26, 2008

/Maureen M. Wallenhorst/

Primary Examiner, Art Unit 1797